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In re Application of :  
Knutzon et al. :  
Serial No.: 09/367,013 : PETITION DECISION  
Filed: August 5, 1999 :  
Attorney Docket No.: CGAB-210-USA :

This is in response to the petition under 37 CFR 1.181, filed February 6, 2004, requesting relief from the withdrawal of claims 189-214 and 285-290 from consideration. The delay in acting on this petition is regretted.

#### BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 on August 5, 1999, and contained claims 1-64. A preliminary amendment was filed on August 5, 1999 canceling claims 1-64 and adding new claims 65- 188. In a first Office action, mailed May 8, 2001, the examiner set forth a restriction requirement under 35 U.S.C. 121 and 372, as follows, and further requiring a species election:

Group I, claim(s) 65-66, 93, 94, 99, 100 and 187, drawn to methods for making oleic acids, linolenic acid, y-linolenic acid, stearidonic acid, and alpha-linolenic acid.

Group II, claim(s) 67, 69-72, 91, 100, 102-105, 126, 131-134, 153, 156, 158-161, 180, 185, 186, and 188, drawn to microbial oil and pharmaceutical compositions.

Group III, claim(s) 97 and 98, drawn to methods for making y-linolenic acid from linolenic acid.

Group IV, claim(s) 73-75, 106-108, 135-137, and 162-164, drawn to nutritional compositions.

Group V, claim(s) 76-78, 110, 111, 138-140, and 165-167, drawn to infant formula.

Group VI, claim(s) 79-86, 112-119, 142-148, and 168-175, drawn to a dietary supplement and substitute.

Group VII, claim(s), 68, 87-88, 101, 121-123, 130, 149, 157, 176, and 177, drawn to a method of treatment.

Group VIII, claim(s) 89, 90, 124, 125, 151, 152, 178, and 179, drawn to a cosmetic composition.

Group IX, claim(s) 92, 127, 154, and 181, drawn to an animal feed.

Group X, claims(s) 95 and 96, drawn to the polypeptides of SEQ ID NO's: 34-40.

Group XI, claim 182, drawn to nucleic acid sequences of SEQ ID NO's: 19, 21, 23, and 25.

Group XII, claim 183, drawn to the polypeptides of SEQ IS NO's: 20, 22, 24, and 26.

On July 31, 2001, Applicant filed a response and elected Group I without traverse and stearidonic acid as the species. On October 12, 2001, the examiner mailed a non-final Office action to applicants rejecting claims 65, 66, 93, 94, 99, 100, and 187; and withdrawing claims 67-92, 95-98, 101-186 and 188 from consideration. The reply to this Office action was filed by applicants on April 12, 2002, adding claims 189-284, and canceling claims 65-160 and 187.

On June 28, 2002, the examiner mailed a final rejection to applicants, in which the examiner rejected claims 215-284, and withdrew claims 189-214 from consideration. The examiner stated in his Office action that new claims 189-214 and 215-284 are drawn to two independent methods which do not relate to a single inventive concept under PCT Rule 13.1. The methods of claims 189-214 are drawn to a method of making a transformed host cell using the nucleic acid sequence of SEQ ID NO: 1. Thus, the special technical feature for the invention of claims 189-214 is the nucleic acid of SEQ ID NO:1. In contrast, the method of claims 215-284 are drawn to a method of making oil, presumably, enriched in stearidonic acid. The special technical feature for the method of claims 215-284 are the transformed host cells produced by the method of claims 189-214. Thus, the inventions of claims 189-214 and 215-284 do not share a common inventive concept under PCT Rule 13.1.

Applicants filed the reply to this Office action, including RCE papers, on October 28, 2002, with a traversal statement concerning the withdrawal. Applicants also cancelled claims 197, 198, 209 and 245-254, and added claims 285-296; claims 285-290, 293 and 296 being product claims.

On December 31, 2002, the examiner issued a non-final Office action rejecting claims 215-244, 255-284, 292, and 295; and withdrawing claims 189-196, 199-208, 210-214, 285-291, 293, 294, and 296 from consideration.

In the response filed by applicants on June 30, 2003, reconsideration of the withdrawal was made and claim 297 was added.

On October 6, 2003, a final Office action was mailed to applicants rejecting claims 225-244, 265-284 and 297; allowing claims 215-224 and 255-264; and withdrawing claims 189-214, 285-290 from consideration. It is pointed out that claims 197, 198 and 209 were actually cancelled in the previous response of June 30, 2003.

## DISCUSSION

This application was filed under 35 U.S.C 371 and as such the requirement for Unity of Invention is as follows: An international or a national stage application is considered to have unity of invention where there exists a “special technical feature” that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2:

#### PCT 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

*See Annex B, Part 2 of the PCT Administration Instructions*

MPEP 1850 states *Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims and* (i) *If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;* (ii) *If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered.* *If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part I “Instructions Concerning Unity of Invention” MPEP AI-6 (Rev. 1. Feb. 2003).*

37 CFR 1.475(b)-(d) provides guidance for treatment of second and subsequent products and methods.

(b) *An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:*

- (1) *A product and a process specially adapted for the manufacture of said product; or*
- (2) *A product and process of use of said product; or*
- (3) *A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or*
- (4) *A process and an apparatus or means specifically designed for carrying out the said process; or*
- (5) *A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.*

(c) *If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention*

*might not be present.*

*(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).*

Applicants argue that claims 189-196, 199-208, and 210-214, and 285-290 are within the elected invention under PCT rules. The Office action of June 28, 2002 stated that claims 189-214 and 215-284 were drawn to two independent methods which do not relate to a single inventive concept under PCT Rule 13.1. The Office action of December 31, 2002 stated that claims 185-214, 291, and 294 were not within Group I elected by applicants. Applicants argue that the single inventive concept to which all the claims relate is a product that is a microbial cell culture with an altered fatty acid profile by virtue of expression of a sufficient amount of a delta 6-desaturase, and that claims 189-214 relate to a method for production of this product, claims 215-284 relate to a method of use of this product to produce an oil with an altered fatty acid profile, and claims 285-290 relate to the microbial culture itself. Applicants point out that these claims were not restricted from each other in the original restriction requirement, and the subsequent withdrawal of claims 189-196, 199-208, 210-214, and 285-290 was timely traversed. Applicants state that they have presented claims for a method of making a given product, claims for a method for use of that product, and claims to the product itself. Applicants argue that since the MPEP states that these sets of claims share unity of invention under PCT rules, applicant should get relief from the withdrawal of claims 189-214 and 285-290 from consideration.

The examiner correctly states in his Office action of June 28, 2002, that new claims 189-214 and 215-284 are drawn to two independent methods which do not relate to a single inventive concept under PCT Rule 13.1. Therefore, no unity of invention existed between these two groups. The special technical feature between these two groups would be the product. However, there was no product present at the time of election which precluded there being a special technical feature which unites the different groups. Applicant later added product claims after the election and examination. As the product was added after examination, they were withdrawn from consideration. These product claims, withdrawn by original presentation, have not been searched and therefore, cannot constitute a special technical feature. Applicants cannot add a special technical feature after the election.

## DECISION

The petition is **DENIED**.

**Applicants remain under obligation to file a proper reply to the Notice of Appeal of February 9, 2004, within the time period set therein or as may be extended under 37 CFR 1.136(a).**

Should there be any questions about this decision please contact Marianne C. Seidel by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.



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